

REMARKS/ARGUMENTS

Upon entry of the present amendment, claims 1-3, 5-8, 15-16, 18-19, 21-23 and 25-27 are pending.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION OF THE CLAIMS

Claims 1 and 27 are rejected under the doctrine of obviousness-type double patenting over claims 48, 49 and 54 of copending application 09/772,607 (“the ‘607 application”). In particular, in response to Applicants’ assertion in the prior Amendment that the amendment to claims 1 and 27 to recite that the claimed formulations contain DPPC renders the rejection moot, the Examiner “contends that page 7 of the ‘607 application gives examples of isotonic agents, preservatives and buffers suitable for use with the GLP-1 compounds” (page 4 of Office Action).

Applicants respectfully traverse this rejection.

The disclosure on page 7 of the ‘607 application cited to by the Examiner is reproduced below:

“Examples of isotonic agents are sodium chloride, mannitol and glycerol.

Examples of preservatives are phenol, m-cresol, methyl p-hydroxybenzoate and benzyl alcohol.

Examples of suitable buffers are sodium acetate and sodium phosphate.”

It is the Applicants’ position that there is nothing in this disclosure that either teaches or suggests a formulation suitable for pulmonary administration that contains DPPC. Accordingly, Applicants respectfully request that this rejection be withdrawn.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. §102 REJECTIONS

- A. The Examiner has rejected claims 1-3, 5-8, 15-16, and 18-19 under 35 U.S.C. §102(e) as being anticipated by Knudsen et al. (USPN 6,268,343). In particular, in response to Applicants’ assertion in the prior Amendment that the amendment to claims 1 and 27 to recite that the claimed formulations contain DPPC renders the rejection moot, the Examiner “contends that claim 29 of the ‘343 patent gives examples of isotonic agents, preservatives and buffers suitable for use with the GLP-1 compounds” (page 6 of Office Action).

Applicants respectfully traverse this rejection.

Claim 29 of the '343 patent is reproduced below:

"A pharmaceutical composition of claim 28, further comprising an isotonic agent, a preservative and a buffer."

It is the Applicants' position that there is nothing in this disclosure that either teaches or suggests a formulation suitable for pulmonary administration that contains DPPC. Accordingly, Applicants respectfully request that this rejection be withdrawn.

- B. The Examiner has rejected claims 21-23 and 25-27 under 35 U.S.C. §102(e) as being anticipated by Hughes et al. (USPN 6,720,407).

Applicants respectfully traverse this rejection.

Independent claim 27 (from which claims 21-23 and 25-26 depend) recites that the claimed dry formulation contains inter alia "a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms". Thus, while the Examiner notes that the present specification describes the term lipophilic substituent as comprising 4-40 carbon atoms, **the rejected claims recite that the lipophilic substituent is from 14-18 carbon atoms.**

Accordingly, the Examiner's citation to SEQ ID NO:3 in the '720 patent as containing a 6-10 carbon unbranched acyl group does not anticipate claims 21-23 and 25-27 and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that the application is now in condition for allowance and issue. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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